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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/751,765

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Pierluca Lombardi

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

06/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/751,765	<b>Applicant(s)</b> LOMBARDI, PIERLUCA	
	<b>Examiner</b> ANDREW M. GILBERT	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13, 15, 16, 18-21 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 15, 16, 21 and 23-26 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/31/2008</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Acknowledgments***

1. This office action is in response to the reply filed on 3/31/2008 and 3/10/2008.
2. In the reply, the Applicant amended claims 13, 15 and 21; cancelled claims 14 and 22. Claims 19-20 were previously withdrawn.
3. Thus, claims 13, 15-16, 18, 21, 23-26 are pending for examination.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on 3/31/2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 13, 21, 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Treu (5630935).
7. Treu discloses an apparatus for regulating pressure applied during a medical procedure, comprising: an inelastic housing (Fig 4a,b) enclosing an inner volume, the housing having a first and second end (respective ends of syringe 135) wherein the housing (135) comprises a cylindrical inelastic housing enclosing the inner volume and a plunger (135); an aperture (opening of 138, 150 of syringe 135) in the housing for

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conveying pressure from the housing during medical procedure, and a pressure-operated valve (78) coupled between the inner volume of the housing and a space outside of the inner volume of the housing for allowing pressure to escape from the inner volume of the housing through the valve when pressure in the housing exceeds a threshold, whereby the valve releases pressure from within the inner volume of the housing (col 9, Ins 56-67); wherein the pressure-operated valve is adapted to allow selection of the threshold, during use, from a plurality of different thresholds (130; 144; col 9, Ins 56-67; wherein the user controls the force and thus the threshold via the adjustment member); wherein the pressure-operated valve comprises: an opening (opening of 136 that contacts diaphragm 140) in the housing; a plunger (140) disposed within the inner volume of the housing; a spring (144) disposed within the inner volume of the housing, wherein the spring is positioned between the second end of the housing and the plunger (Fig 4a-b), wherein the plunger in a rest position is between the opening and the aperture (Fig 4a-b), a pressure operated valve communicated with the inner volume of the housing and adapted to release pressure from the inner volume when pressure in the inner volume is above a threshold (Fig 4a-b; col 9, Ins 56-67; wherein when pressure rises the plunger 140 moves allowing fluid to move into 136 thus releasing pressure); wherein the threshold is set by a spring exerting a force which must be overcome to exceed the threshold (col 9, Ins 56-67), and further comprising a movable member (140) which can be positioned between at least two different positions corresponding to different forces of the spring which must be overcome to exceed the threshold (col 9, Ins 56-67); wherein the movable member only causes pressure to be

released once the force is overcome (col 9, lns 56-67). Additionally, see Response to Arguments below.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 13, 15-16, 21, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (4623335) in view of Treu (5630935). Jackson discloses an apparatus for regulating pressure applied during a medical procedure, comprising: an inelastic housing (24) enclosing an inner volume, the housing having a first and second end (respective ends of syringe 24 and 26) wherein the housing (24) comprises a cylindrical inelastic housing enclosing the inner volume and a plunger (25); an aperture (18) in the housing for conveying pressure from the housing during medical procedure, and a pressure-operated valve (22; Fig 2) coupled between the inner volume of the housing and a space outside of the inner volume of the housing for allowing pressure to escape from the inner volume of the housing through the valve when pressure in the housing exceeds a threshold, whereby the valve releases pressure from within the inner volume of the housing (Figs 1-4; col 5, lns 32-col 6, lns 3); wherein the pressure operated valve comprises an opening (52), a plunger (60) disposed within the inner volume of the housing; a spring (52) disposed within the inner volume of the housing, wherein the

spring is positioned between the second end of the housing and the plunger (Fig 2), wherein the plunger in a rest position is between the opening and the aperture (Fig 2), and wherein as fluid is inserted into the inner volume of the housing via the aperture, increased pressure within the inner volume of the housing moves the plunger toward the opening (Figs 1-4; col 5, lns 32-col 6, lns 3); wherein the opening is positioned in a side of the housing providing access to the inner volume of the housing (52; Fig 2), wherein at normal pressure the opening is closer to the second end than the plunger and wherein as pressure within the inner volume of the housing increases so as to move the plunger past the opening (Figs 1-4), the pressure within the inner housing is released through the opening (Figs 1-4; col 5, lns 32-col 6, lns 3); wherein the threshold is set by a spring exerting a force which must be overcome to exceed the threshold (Figs 1-4; col 5, lns 32-col 6, lns 3).

10. However, Jackson does not disclose that the pressure operated valve is adapted to allow selection of the threshold, during use, from a plurality of different thresholds; wherein a movable member which can be positioned between at least two different positions corresponding to different forces of the spring which must be overcome to exceed the threshold. Treu teaches that it is known to have a pressure operated valve adapted to allow selection of the threshold during use from a plurality of different thresholds (130; 144; col 9, lns 56-67; wherein the user controls the force and thus the threshold via the adjustment member) and a movable member (140) which can be positioned between at least two different positions corresponding to different forces of the spring which must be overcome to exceed the threshold (col 9, lns 56-67) for the

purpose of controlling the threshold value. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spring system as taught by Jackson with the spring system adapted to allow selection of the threshold as taught by Treu for the purpose of controlling the threshold valve.

### ***Response to Arguments***

11. Applicant's arguments filed 3/10/2008 have been fully considered but they are not persuasive.

12. The Applicant argues that Treu discloses only used the syringe for sample collection and does not have a plunger for pressurizing the inner space of the syringe.

13. In response to applicant's argument that, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The syringe (135) has a plunger that is fully capable of pressurizing the inner space of the syringe barrel. Treu discloses that the syringe (135) is capable of sample collection by pulling fluid into the syringe barrel via the plunger (ie pull the plunger out creates a vacuum in the syringe barrel pulling fluid into the barrel). Thus, the plunger is disclosed as applying pressure to the inner volume. One of ordinary skill in the art at the time of the invention would recognize that the syringe (135) as shown and disclosed in Treu is fully capable of having its plunger act in the opposite manner to exert a pressurized force onto a fluid in the reservoir space of the syringe barrel to expel fluid.

***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767